amal**sed**® direct- dry

INSTALLATION, OPERATION & CARE MANUAL

medentex
The Experts in Dental Services

Contact information

medentex LLC

181 East Halsey Road
Parsippany
NJ 07054, USA

Telephone : (1) 888-640-2527
Fax : (1) 847-257-4432
E-Mail : info@medentex.com
Website : www.medentex.com

Disclaimer and Exclusion of Liability

medentex cannot be made liable for damages resulting from failure to observe the information contained in this manual, modifications to the product not approved by medentex or the use of spare parts not manufactured or approved by medentex.

Table of Contents

Contact information 2

Disclaimer and Exclusion of Liability 2

Table of Contents 3

Section I – Introduction.....5

General Information 5

Conventions used in this manual 5

Explanation of symbols used on equipment and in this manual 5

Safety Instructions 6

Proper use..... 6

Qualifications of personnel 6

Risk posed by waste water from dental practices 6

Safety notices and labels on the products 6

Classification & Certification 7

Product definition and description..... 8

Section II – Pre-Installation.....9

Site Requirements 9

Typical Installation Options..... 9

amal**sed**® direct – Dry..... 9

Section III – Installation & Initial Operation 10

Illustrated Parts Breakdown and Replacement Parts List 10

amal**sed**® direct S - Dry Kit:.....10

amal**sed**® direct L - Dry Kit 11

Installation 12

amal**sed**® direct – Dry (Drain-line) 12

Section IV – Care 13

Replacing the amalgam separator 13

Cleaning and disinfecting agents 15

Section V – User Service Information 16

Individual Product Information 16

Troubleshooting 16

Section VI - Warranty & Product Support Services 17

User's log - Daily cleaning actions 18

User's log - Amalgam separator replacement details.....19

Section I – Introduction

General Information

This manual contains the installation, operation, care and repair instructions, and user service information for medentex dental amalgam separator kits:

- amal**sed**® direct S - for up to 3 operating units or 2 users*
- amal**sed**® direct L - for up to 6 operating units or 4 users*

The amal**sed**® direct is designed to provide trouble-free service when installed, operated and cared for according to the procedures set forth in this manual.

Conventions used in this manual

⚠	WARNING Warning of a harmful situation Possible consequences: Danger to health.

!	NOTICE Notice about a harmful situation Possible consequences: Damages to product or surrounding objects.

Explanation of symbols used on equipment and in this manual

Attention. Warning of dangerous or immediate danger to health.

CE compliant medical product complying with ISO 13485.

Safety Instructions

Proper use

The amal**sed**® direct is a multi-fit amalgam separator that acts as a central point for cleansing waste water in dental practices and separating amalgam from waste water by sedimentation. It is designed to remove 99.2% of waste amalgam from dental waste water. The medentex amal**sed**® green amalgam separator cartridge is **ISO 11143** approved and test results can be delivered upon request.

Qualifications of personnel

This manual is intended for trained dental staff and dental technicians who are aware of regulations and standard application to the place of installation.

!	NOTICE
	Trained and authorized personnel with appropriate plumbing qualifications only are permitted to install and commission the amal**sed**® direct - amalgam collector kit!

!	NOTICE
	The amalgam separator must be replaced by accredited service technicians or instructed members of dental office staff only (dental office staff must be briefed by the service technician during product installation and commissioning).

Risk posed by waste water from dental practices

Waste water from dental practices including water used during dental treatment can contain harmful heavy metals and potentially infectious materials.

⚠	WARNING
	Always wear protective clothing when working with the amal**sed**® direct and when replacing the amalgam separator(s). Protective clothing includes protective gloves and facemask that are supplied with the installation kit.

Safety notices and labels on the products

Warning label on the amalgam separator:

CAUTION BIOHAZARD	WARNING
	Attention. Warning of infectious / hazardous wastes.

Classification & Certification

Proprietary Name:	amalsed® max; medentex amalsed; medentex SRAB 99S
Classification Name:	Unit, Operative Dental, Accessories.
Product Code:	NRD
Device Class:	1
Regulation Number:	872.6640
Medical Specialty:	Dental
Registered Establishment Name:	MEDENTEX GMBH
Owner/ Operator:	medentex GmbH
Owner/Operator Number:	10036262
Establishment Operations:	Manufacturer

amal**sed**® green - medical product complying with CE-Norm.
Certification body No: **0434** – Det Norske Veritas (DNV)

amal**sed**® green - amalgam separation efficiency according to **ISO 11143**.

Product definition and description

Technical description and data

The amal**sed**® direct is an amalgam collector kit, designed to be connected to any existing dental vacuum system.

SPECIFICATIONS		
Product Name	amal**sed**® direct S	amal**sed**® direct L
Number of Amalgam separators	1	2
Max. Number of operatories / Users to be connected simultaneously.	3 ops. / 2 users	6 ops. / 4 users
Tray dimensions H x W x D [inches]	9.75” x 15” x 13”	9.75” x 15” x 13”
Separator dimensions H x W x D [inches]	7” x 10.75“ x 6.5”	7” x 10.75“ x 6.5”
Air-Water Separator dimensions H x W x D [inches]	15.5” x 10.5“ x 9”	15.5” x 10.5“ x 9”
Flow rate [gal/min.]	0.8	1.6
Connection size [In]	1”	1”
Amalgam separation efficiency	99.2%	99.2%
Expected time to fill	1 year	1 year

Section II – Pre-Installation

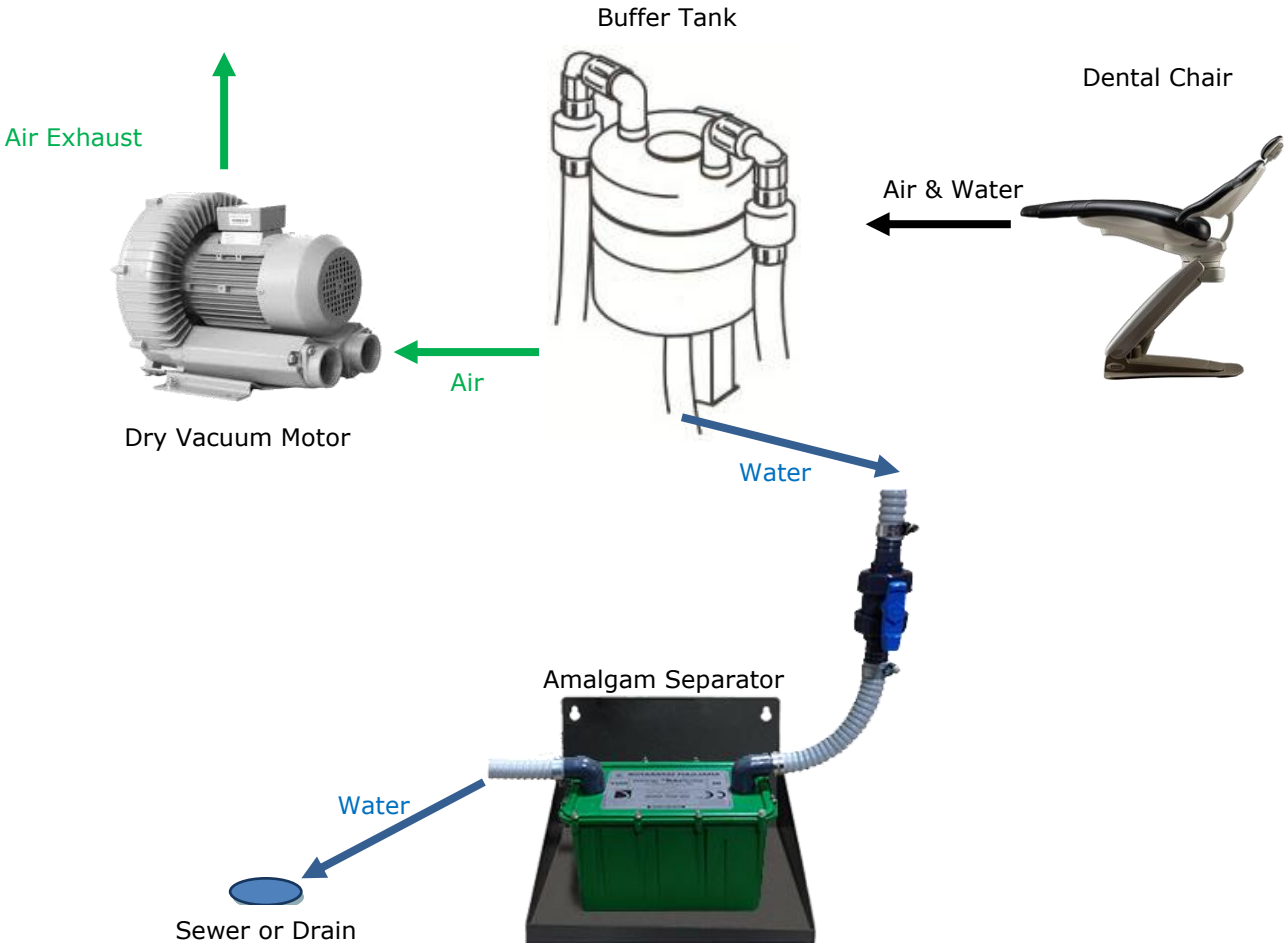
This chapter assists in making an easy and sound installation. For direct assistance, please contact an authorized dealer or a medentex technical service representative.

Site Requirements

The amal**sed**® direct is designed to enable easy installation. All basic components are delivered within the starter kit. Prior to installation, the following requirements must be available:

Typical Installation Options

amal**sed**® direct – Dry *(Product ID: A0US1803 & A0US1804)*



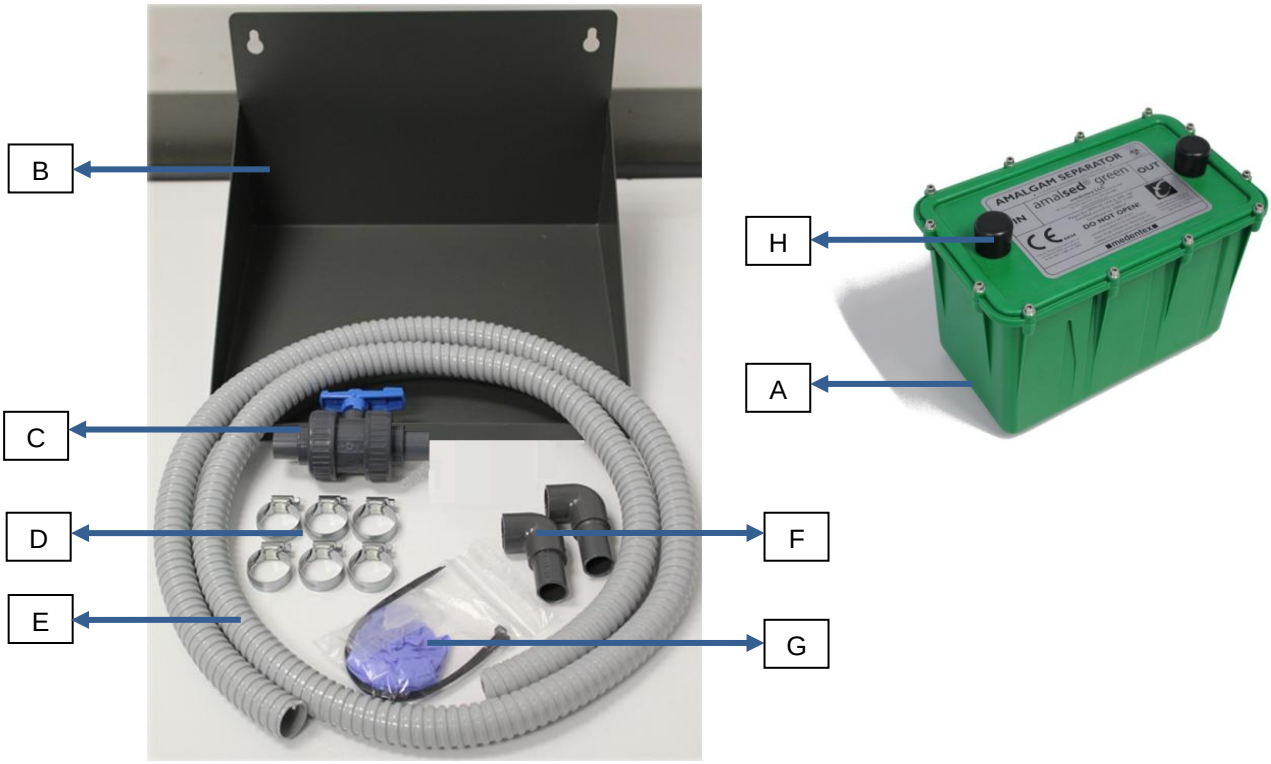
	NOTICE
!	Do not use pressurized air or water with a medentex amalgam separator! The amal**sed**® direct is a sedimentation-device where waste water passes through the amalgam separator with the speed of gravity!

Section III – Installation & Initial Operation

Illustrated Parts Breakdown and Replacement Parts List

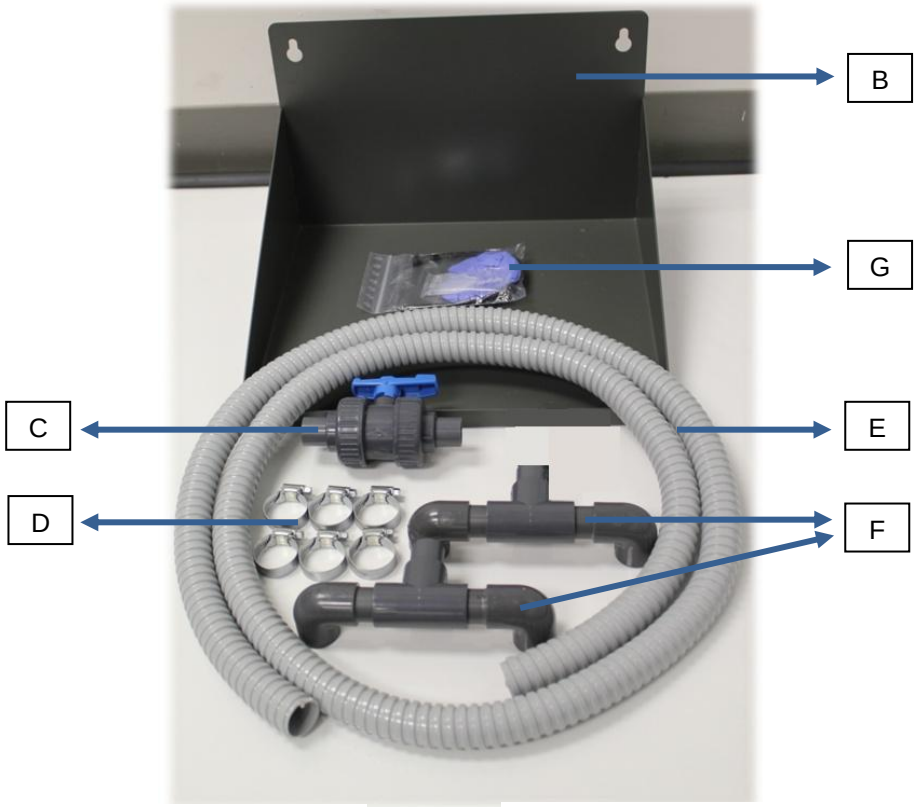
!	NOTICE
	All components listed and described in this chapter are available as repair parts.

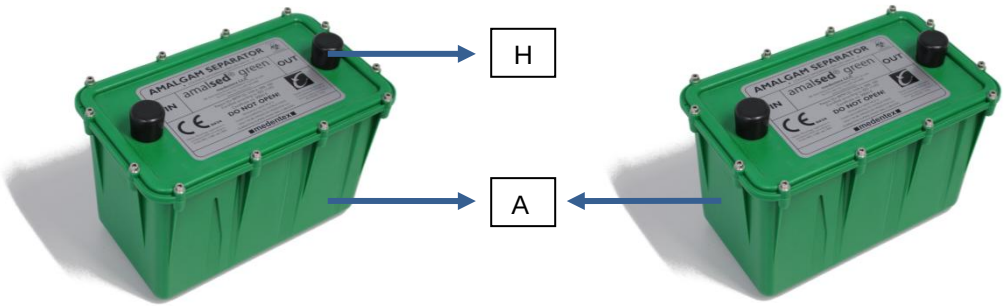
amal**sed**® direct S - Dry Kit:



ITEM	NAME	TYPE	ARTICLE ID	QTY
A	Amalgam Separator	amal**sed**® green	A0US0001	1
B	Tray	-	A0100002	1
C	Service Valve	1” slip fit ends	A1000051	1
D	Hose Clamps	-	A1000001	6
E	Hose	5’ x 1” double walled	A1000009	1
F	90° slip fit hose adapter	1” male x 1” female	A1000053	2
G	Separator service pack	Gloves, Silicone	AUS00001	1
H	Separator cap	1” Female Slip Fit	A2200004	2

amal**sed**® direct L - Dry Kit





ITEM	NAME	TYPE	ARTICLE ID	QTY
A	Amalgam separator	amal**sed**® green	A0US0001	2
B	Tray	-	A0100002	1
C	Service Valve	1” slip fit	A1000051	1
D	Hose Clamps	-	A1000001	6
E	Hose	5’ x 1” double walled	A1000009	1
F	Plumbing Bridge	1” slip fit	A1000050	2
G	Separator service pack	Gloves, Silicone	AUS00001	1
H	Separator cap	1” Female slip Fit	A2200004	2

Installation

	WARNING
⚠	• Always wear protective clothing when installing the amal**sed**® direct. Protective clothing includes protective gloves and protective mask. • Shut down vacuum pump and allow existing system to drain.

amal**sed**® direct – Dry (Drain-line)

1. Mount tray to wall (under buffer tank drain) as shown on page 10.
2. Place amalgam separators on tray.
3. Cut hose in two pieces with correct length for both, intake line and output line to drain.
4. Push hose clamps over the hose
5. Connect hose clamps with in-line connector bridge and drain-line connector bridge or 90° elbows.
6. Fasten hose clamps – Do not over tighten!
7. Connect in-take to service valve (C) in between and the input of the amalgam separator
8. Connect output tubing of the amalgam separator to drain / sewer or P-Trap
9. Make sure output tubing to drain is positioned to allow water to flow downwards. (see above)
10. Open service valve and test system for leaks!

	NOTICE
!	Installation must comply with local plumbing codes! – Test system for leaks after installation!

Section IV – Care

!	NOTICE Please regularly verify if all connections are free of leakages. (View Section V for troubleshooting)

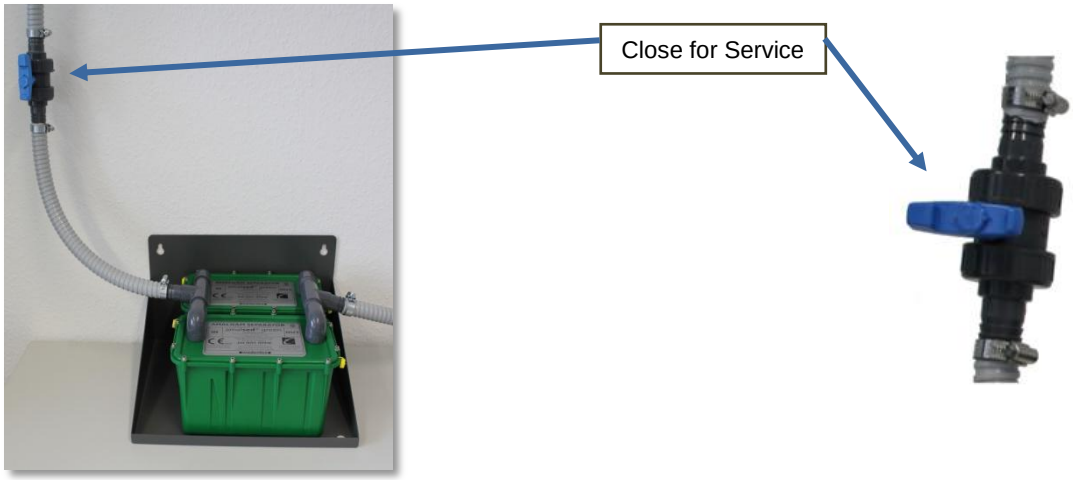
Replacing the amalgam separator

⚠	WARNING The amalgam separator can only be replaced by trained service technicians or by instructed members of the dental practice staff.

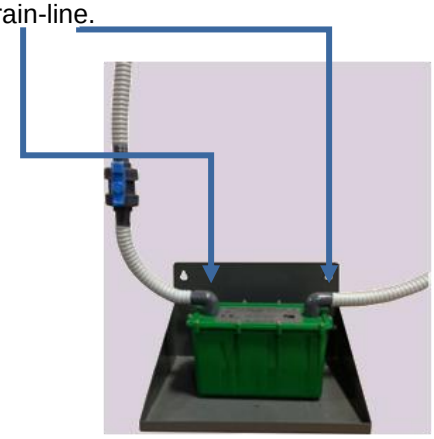
⚠	WARNING Wear protective clothing when replacing the amalgam separator. Protective clothing includes protective gloves, protective goggles and a laboratory coat.

!	NOTICE Do not allow the amalgam separator to exceed the maximum designated service life. medentex or a company authorized by medentex will inform you the service life of your amalgam separator when commissioning the amal**sed**® direct.

1. Before replacing the amalgam separator clean the suction system with a non-foaming cleaning agent for vacuum systems.
2. Shut down vacuum pump!
3. Close service valve. Wait 1 minute.



4. Detach both in-line and drain-line.



5. Close the inlet and outlet ports with original sealing caps. The sealing caps must clearly lock into place.

6. Store the used amalgam separator in the original packaging.
medentex will arrange for pick-up service (free of charge)

7. Before re-connecting the new amalgam separator(s), lubricate the o-rings on the intake/output ports. Reconnect the lines onto the ports of the amalgam separator(s).

8. Open service valve and restart vacuum pump.
9. Verify that all connections are tight and free of leaks!

!	NOTICE
	Check that all connections are tight and do not leak before starting vacuum!

Cleaning and disinfecting agents

Safety-relevant notes on cleaning

To prevent microbiological contamination, the built up of deposits and soiling it is imperative that the suction hoses, waste water lines and the amalgam separation system are cleaned daily with special cleaning agents for dental suction systems.

	CAUTION
	Use only generally accepted cleaning agents for dental suction systems. medentex recommends the use of non-foaming and bleach/chlorine free cleaning agents. Carefully follow the directions on the cleaning agent of your choice. Only practice personnel that have received appropriate instructions may apply the cleaning agent. medentex highly recommends non-foaming cleaning agents. Please clean your suction lines daily and see User's log: daily cleaning actions, attached at the end of this document.

Section V – User Service Information

The following troubleshooting charts should be used when attempting to solve amal**sed**® direct operational problems. If the problem is not addressed in the trouble shooting chart or cannot be isolated by performing the suggested procedures, contact medentex or your local medentex full-service dealership.

Individual Product Information

Be prepared to supply the following product information:

Model Name:	
Article Number:	
Serial Number:	
Installation Date:	

Troubleshooting

Amalgam separation starter kit				
SYMPTOM	POSSIBLE CAUSE	SOLUTION	T[1]	PS[2]
Drain line blocked	Separator clogged	Inform medentex and exchange separator immediately	x	x
Leakages at connections	Lose hose clamps	Tighten all hose clamps and dry system from outside to detect leakages immediately.	x	
	Damaged or faulty components	Exchange damaged / faulty components	x	
Service valve clogged or does not turn	Service valve clogged	Unscrew Service valve-head and rinse		x
		Detach service valve to clean, replace service valve if necessary	x	

[1] Technician
[2] Practice Staff

Section VI - Warranty & Product Support Services

In the event that you experience difficulty with the application or operation of any of our products, please contact our customer service department at 888-640-2527 or e-mail to info@medentex.com. Please note serial numbers of your product.

If we cannot resolve the issue by telephone, we will arrange for a representative to contact you.

All medentex products are intended for use solely by licensed dentist. Provided that the end user dentist complies with the instructions provided by or on behalf of the manufacturer and/or medentex, medentex warrants all amalsed® products to be free of defects in material and workmanship from the date of installation for a period of three (3) years on complete unit and five (5) years on all pumps, motors and housings, subject to the following terms and conditions.

These warranties shall cover the replacement or repair, at the option of medentex, for manufacturing defects only. The warranties shall not cover defects or damage resulting from misuse, improper handling, maintenance, or care, correction of improper installation, repair of damage due to improper installation, deterioration due to normal wear and tear, abuse, negligence, accidents, damage in transit, abnormal use, improper cleaning, or failure to comply with operating, maintenance or installation instructions. Failure to use medentex or manufacturer authorized parts or a medentex authorized repair facility voids this warranty.

Liability is limited to repair or replacement of the defective product and shall be at the discretion of medentex. All other liabilities, in particular liability for damages, including, without limitation, consequential or incidental damages, are excluded. These warranties are in lieu of all other warranties, express or implied, including any implied warranties of merchantability, fitness for a particular purpose, design or suitability. Except for the express warranty described herein, medentex makes no warranty, guarantees or representations with respect to the products covered hereby, express or implied, including, but not limited to, any warranty of merchantability, fitness for a particular purpose, design or suitability with respect to the products or any other goods, services or other materials provided by medentex.

medentex's sole liability shall be limited to repair and replacement of defective parts pursuant to the warranty described above and in no event shall medentex be liable for any damages, liability, or expense, including without limitation, attorney's fees, loss of profits, or indirect, special, consequential, incident or punitive damages, even if medentex was advised of the possibility of such damages.

Parts repaired or replaced on a product that is in warranty will be warranted for the duration of that product's original warranty.

NO EMPLOYEE, REPRESENTATIVE, AGENT, OR DISTRIBUTOR IS AUTHORIZED TO CHANGE THIS WARRANTY IN ANY WAY OR TO GRANT ANY OTHER WARRANTY.

User’s log - Daily cleaning actions

DATE	NAME	DAILY CLEANING WITH AN APPROVED CLEANING AGENT

User’s log - Amalgam separator replacement details

Replace the amalgam separator according to the terms and conditions of your recycling agreement with medentex.

DATE	STAFF NAME	SERIAL NUMBER OLD	SERIAL NUMBER NEW

Parsippany, NJ Facility 2011

medentex LLC

181 East Halsey Road
Parsippany
NJ 07054, USA

Telephone : (1) 888-640-2527
Fax : (1) 847-257-4432
E-Mail : info@medentex.com
Website : www.medentex.com

Version Apr/2015